

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/B2004/001701International filing date (day/month/year)
15.04.2004Priority date (day/month/year)
15.04.2003International Patent Classification (IPC) or both national classification and IPC
A61K39/00, C07K14/47Applicant
AVENTIS PASTEUR, LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/001701

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☒ in written format
☒ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☒ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/001701

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 36-39

because:

☒ the said international application, or the said claims Nos. 31,52-57 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 36-39

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/IB2004/001701

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------------------------|
| Novelty (N) | Yes: Claims | 2-25,27-30,32-35,40-57 |
| | No: Claims | 1,26,31,58-63 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-35,40-63 |
| Industrial applicability (IA) | Yes: Claims | 1-35,40-63 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item I

Basis of the report

Sequence listings, 4 pages, as originally filed are also included in the basis of the opinion/report.

Sequence listings filed, 41 pages, Seq id 1-106, with the letter of 06.01.05, are filed after the filing date of the application and do not form part of the description and will not be annexed to this communication/report (Rule 13ter.1(f) PCT).

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

- No search was carried out for the claims 36-39. Consequently no opinion will be formulated for the subject-matter of these claims.
- Claims 31,52-57 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 01/47959 A

D2: JAEGER D. ET AL.,: CANCER IMMUNITY, vol. 2, 28 June 2002 (2002-06-28), page 5

D3: JAGER DIRK ET AL: CANCER RESEARCH, vol. 61, no. 5, 1 March 2001 (2001-03-01), pages 2055-2061,

D4: WO 2004/037284 A

2. The sequence of BFA5 (NY-BR-1) is known from D3 which identified the NY-BR-1

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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protein as a tumor-antigen in breast cancer.

D1 furthermore describes the use of NY-BR-1 (seq id 23) for using it in a vaccine composition for the treatment of cancer, see e.g. claims 84 ff. and page 23, Example 22.

Novelty for the subject-matter of claims 1,26,31,58-63 can therefore not be acknowledged (Article 33(2) PCT).

In addition the disclosure of D2 identifies the tumor antigen NY-BR-1 as potentially relevant for immunotherapy approaches, see abstract and discus.

Therefore it seems that claims 2-25,27-30,32-35,40-57 describes with respect to the cited prior art (D1,D2) subject-matter which is for the person working in the field of cancer immunotherapy standard knowledge and which does not need the input of an inventive step. The requirements of Article 33(3) PCT are thus not fulfilled.

Re Item VI

Certain documents cited

Certain published documents

| Application No Patent No | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
|-----------------------------|--------------------------------------|---------------------------------|---|
| WO-A-2004037284 | 06.05.2004 | 21.10.2003 | 22.10.2002 |

The intermediate document D4 discloses NY-BR-1 peptide sequences for the use in cancer immunotherapy. This document therefore would appear to disclose or make obvious the subject-matter of claims 1-35 and 40-62 and therefore may be relevant in the national or regional phase (e.g. EPO(Article 54/3) EPC)).

Re Item VII

Certain defects in the international application

The specification of an international application should be self-contained without reference to any other document (cf PCT guidelines, C-II,4.17). The expression

"incorporated by reference" found e.g. in the description on page 2, line 21
therefore is not according to the PCT requirements.

Re Item VIII

Certain observations on the international application

- The subject-matter of claim 6 is not clear. The expression "tumor-associated antigen" is not defined by structural features and therefore renders the scope of claim unclear (Article 6 PCT).
The same holds true for the expression "angiogenesis-associated antigen" of claim 11 and for claim 21 for the expression "co-stimulatory molecule".
- Claim 40 is not clear (Article 6 PCT). The expression "nucleic acid hybridizable under stringent conditions..", "fragment", "derivative" is not defined by structural features and therefore renders the scope of the claim unclear.
The same holds true for the subject-matter of claim 62.
- The subject-matter of claims 58 and 62 is no clear (Article 6 PCT). The expression "A DNA molecule comprising the nucleic acid seq id 5 and at least... nucleic acid sequences.. seq id 5" renders the scope of the claims unclear.